

K010636

<b>CIBA Vision.</b> <small>A Novartis Company</small>	CIBA Vision® Corporation 11460 Johns Creek Parkway Duluth, GA USA 30097	Page 1 of 4
<b>Focus® DAILIES® and Focus® DAILIES® Progressives  (nelfilcon A) ONE-DAY Soft Contact Lenses</b>		
510(k) Summary of Safety and Effectiveness		

### 510(k) Summary

#### 1. Submitter Information:

Company: CIBA Vision Corporation  
11460 Johns Creek Parkway  
Duluth, Georgia USA 30097

Contact Person: Alicia M. Plesnarski, RAC  
Senior Specialist, Global Regulatory Affairs

Telephone: 678-415-3924  
FAX: 678-415-3033

Date Prepared: 2 March 2001

#### 2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: Focus® DAILIES® and  
Focus® DAILIES® Progressives  
(nelfilcon A) ONE-DAY CONTACT LENS
- Classification Name: Daily Wear  
Soft (hydrophilic) Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

#### 3. Predicate Device(s):


**Lens Material:** CIBA Vision's Focus® DAILIES® (nelfilcon A) One-Day Contact Lens

Clear lenses: K943487  
VISITINT® lenses: K984273

**Multifocal Design:** CIBA Vision's Focus® DAILIES® Progressives (nelfilcon A) One-Day  
Visitint lenses: K003826

#### 4. Description of Device:

The Focus® DAILIES® and Focus® DAILIES® Progressives (nelfilcon A) ONE-DAY CONTACT LENS are daily wear soft contact lenses intended for single use daily disposable wear. The Dailies lens is a spherical soft contact and the Dailies Progressives lens is a progressive aspheric simultaneous vision soft contact lens. A constant near power profile is incorporated into each Progressive lens across the full range of distance powers. The near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted toward distance. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to +3.00 diopters to see clearly at far, intermediate and near distances.

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The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). The lenses are clear or tinted from edge to edge for visibility purposes with the color additive copper phthalocyanine (CuP).

Lenses are supplied sterile in foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution. The package storage saline may contain up to 0.02% Poloxamer 108.

The physical properties of the lens are:


- Refractive Index: 1.38 (hydrated)
- Center Thickness: 0.09 to 0.17 mm  
(0.10 at -3.00D; 0.15 at +3.00D)
- Light Transmittance: 96% (approx)
- Oxygen Permeability (Dk):  $26 \times 10^{-11}$  (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml x mm Hg)  
[35° C, Fatt corrected]
- Water Content: 69% by weight in normal saline

#### **5. Indications for Use:**

Focus® DAILIES® and Focus® DAILIES® Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not aphakic persons with non-diseased eyes who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

Focus® DAILIES® Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of presbyopia in not aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use daily disposable wear. DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.


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## 6. Description of Safety and Substantial Equivalence

### 6.1 Comparison to Predicate Device (s):

- Lens Material [Predicate Lens current Focus DAILIES (nelfilcon A)]:  
Lens material, chemical composition, formulation (except for addition of 0.5% Poloxamer 108), manufacturing process, packaging and the sterilization method and cycle remain unchanged from the descriptions previously provided in cleared Premarket Notifications 510(k) K963487, K984273, K992446, K003826.
- Lens Design:  
No change to established spherical or multi-focal lens designs.

Comparison to CIBA Vision's Predicate Device		
Table 1:	Predicate Device	
	Focus DAILIES (nelfilcon A) made without surfactant	Focus DAILIES (nelfilcon A) made with surfactant
Lens Material:	nelfilcon A	nelfilcon A
Material Classification:	FDA Group 2 (> 50% H <sub>2</sub> O, nonionic polymer)	FDA Group 2 (> 50% H <sub>2</sub> O, nonionic polymer)
Water Content:	69%	69%
Light Transmittance (clear lenses):	99%	99%
Oxygen Permeability (Dk, Coulometric):	23.4 barrers	24.2 barrers
Power Range:	+20.00 to -20.00D	+20.00 to -20.00D
Visibility Tint:	With or without Copper Phthalocyanine	With or without Copper Phthalocyanine
Manufacturing Method:	Full Mold Cast Lightstream Technology	Full Mold Cast Lightstream Technology
Lens Design:	Spherical and/or Multi-focal	Spherical and/or Multi-focal
Sterilization:	Steam sterilization, Validated autoclave	Steam sterilization, Validated autoclave
Packaging:	Blister Pack	Blister Pack
Package Storage saline solution	Phosphate-acetate buffered saline	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108

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## 6.2 Non-clinical Testing:

Results from a series of physical/chemical tests confirm that DAILIES lenses made with or without the surfactant additive were equivalent and within established specifications for the lenses. Preliminary shelf-life studies confirm the lenses are stable and compatible with the container packaging system, and have established a product shelf-life that will be extended over time following successful completion of testing intervals. Successful results from in-vivo and in-vitro toxicology tests confirm the lenses remain non-toxic and biocompatible with the ocular environment.

## 6.3 Clinical Testing:

A one-month clinical study demonstrated similar overall performance to the concurrent predicate control in the clinically relevant areas of vision, health, comfort and fit when worn for daily wear.

## 7. Substantial Equivalence

DAILIES lenses made with or without a surfactant additive are equivalent and within established specifications for the lens. The lenses maintain clinical performance expectations, established physical/chemical characteristics, and are stable and biocompatible with the ocular environment.

Any difference which may exist between lenses made with or without the surfactant additive do not adversely effect the established performance characteristics and safety and effectiveness profile of the device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 23 2001

Ms. Alicia M. Plesnarski, PAC  
Senior Specialist, Global Regulatory Affairs  
CIBA VISION Corporation  
11460 Johns Creek Parkway  
Duluth, GA 30097-1556

Re: K010636  
Focus® DAILIES® (nelfilcon A) and Focus® DAILIES® Progressives (nelfilcon A)  
One-Day Soft Contact Lenses.  
Regulatory Class: II  
Product Code: 86 MVN  
Dated: March 2, 2001  
Received: March 5, 2001

Dear Ms. Plesnarski:

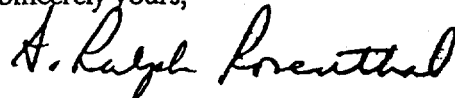
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive style with a large, stylized "A" and "R".

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## INDICATIONS FOR USE STATEMENT

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510(k) Number:

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(nelfilcon A) One-Day Contact Lens

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Concurrence of CDRH, Office of Device Evaluation (ODE)

5106  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K 010636

JS

Prescription Use:

☒ or

Over the Counter Use

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